

ABRATECH® CORPORATION

FROM NEW TECHNIQUES TO NEW KNOW LEDGE ®
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Dear Potential Research Participant:

Thank you for your interest in Sleep / Narcolepsy Research Project. The information given below will tell you more about our study.

The Study:

Abratech Corporation, under a contract from the National Institute of Neurological Disorders and Stroke, is studying a group of normal individuals and individuals with Narcolepsy to make improvements in analysis of sleep, using evoked responses. Evoked responses are electrical brain-waves that can be detected by electrodes placed upon the scalp. One example is the standard Auditory Evoked Response (AER), a commonly used method of testing hearing and brain function related to hearing. Among other things, the test determines how long it takes certain brain signals to travel from one part of the brain to another. Newer computer methods to be tested may improve the usefulness of the AER test in detecting problems related to sleep.+

The Procedure:

If you agree to be in this study, the following will occur:

a) You will complete a questionnaire concerning your hearing, vision and other factors that might interfere with this study.

You will be asked for a brief medical history related to the study. In order to confirm that you have Narcolepsy, Abratech researchers will need to speak with the physician treating you. Attached is an authorization form that you would sign to allow your physician to release the information about your Narcolepsy.

You will be asked to list any medications you are currently taking (birth control medicines are not to be listed). You should not change any medication use if you decide to participate in the study. Abratech just wants to know about the medications in case something might affect the readings.

You will also complete the Epworth Sleepiness Scale. This questionnaire is used routinely at sleep centers such as the Stanford Sleep Research Center. Your answers may be reviewed by a physician associated with the study.

b) You will be asked to take a standard hearing test, even though there is nothing wrong with your hearing and you may be asked to take a standard vision test, even though there is nothing wrong with your vision. The tests may be repeated during or after the recording session.

c) After you have given written consent, up to twelve (12) sensors will be attached to the surface of your scalp and neck. The sensors will be held in place by a soft paste that easily washes out with water. Before the sensors are put in place, the scalp regions will be gently cleaned with either an alcohol swab or a mild grit. The sensors will be attached to a computer that will record your brain waves in response to sounds.

d) All recordings will be done in a 6.5' x 6.5' Abratech soundproof recording room. During the recordings, you will be in the recording room, and should lie quietly (or nap if you are requested to do so), while listening to clicking sounds or short tone-bursts through tubing in comfortable earplugs, or from wall-mounted loudspeakers. These sound signals will produce brain-waves from different regions of your brain. By recording these brain signals or responses, Abratech's researchers will be able to tell how long signals take to travel from one part of your brain to another. They want to see whether these signals change during the daytime recording sessions or during the night.

e) Participation in this portion of the study will take a total of from two (2) to four (4) hours, in the daytime.

Depending upon the results, you may be asked to return for further, overnight, testing. For overnight testing you will change into your own pajamas or sweat clothes, and then sleep in a comfortable bed overnight after the electrodes have been placed. While sleeping, electrodes will record your brain waves, muscle activity, and heart rate. A video tape recorder will record the degree of body movement. During the night you can get up after the electrode wires are disconnected.

f) Some participant data might be analyzed at Stanford. All data will be coded to protect participant privacy and identity. The coded data will also be analyzed by Abratech employees, and by qualified consultants to Abratech.

g) It is possible that the recordings could show some unusual brain wave activity. You would be given the opportunity to choose whether you would want those results.

The Possible Risks:

a) There are no known risks or discomforts from the brain-wave procedures other than those that might occur as a reaction to applying the electrodes to the skin. Such reactions might be a rare allergic reaction to the gel.

b) There is a very small chance that the rapidly-repeating sounds may trigger an epileptic seizure if you have epilepsy that was previously unknown to you. This risk is very small because the sounds are not very loud and this is a very rare condition. You would need to inform the Research Associate doing the testing if you have any reason to believe you may have epilepsy, or if any family members have a history of epilepsy, or if you are taking epileptic medication.

c) If you feel unwell at any time during the testing, you would inform the Research Associate. The testing can be temporarily halted or completely stopped, for any reason, and at any time, just by asking the Researcher Associate who is conducting the test.

d) The clicking sounds or tones heard through the earphones are not known to cause any hearing problems. However, sounds which are very much louder (for example, loud rock music or jack hammers) can give temporary changes in one's ability to hear soft sounds. Hearing tests will be used to detect such changes during the study in case your hearing is unusually sensitive in this regard.

e) Private information would be gathered about you. That information would be kept as confidential as possible under the law. No individuals are ever identified in any reports or publications resulting from this study. The data from the testing might be used for other research projects with the understanding that it will be coded and used with the same confidentiality.

f) Were you to need emergency medical attention for any reason while at Abratech, the personnel would call 911 and summon Dr. Jewett, a physician. If you were injured as a result of participating in this study, treatment would be made available. The costs of such treatment may be covered by Abratech Corporation depending on a number of factors. Abratech does not normally provide any other form of compensation for injury.

The Possible Benefits:

There would be no direct benefits to you for participation in this study. The purpose is to improve methods to study brain activity during sleep and this might benefit future patients. Therefore, subjects participating in this research may, through their efforts, be helping others.

The Possible Alternatives:

The alternative to participation is to say no.

Reimbursement:

You will be reimbursed for daytime testing at the rate of \$25/hour, and nighttime testing at \$250/night. If you need transportation to and from Abratech, it will be provided or a travel allowance will be granted.

Rights:

Participation in this research is voluntary. You have the right to refuse to participate, or to withdraw at any time in this study, without prejudice. You will be given a copy of the Consent Form.

Bring a Friend:

Our study will be improved if we can record a comparison participant of the same gender and approximately the same age as the primary participant who has Narcolepsy. The comparison participant should not have Narcolepsy. We have the ability at Abratech to record two participants at the same time, for both our day and night studies. If you have a friend who might like to act as your comparison participant, please have your friend contact Abratech for more information. Your friend can call our Research Coordinator, James Obayashi, at (415) 289-7458, who will answer any questions and then mail your friend further information about this study. The comparison participant will also be reimbursed for daytime testing at the rate of \$25/hour, and nighttime testing at \$250/night.

Questions:

If you have any questions about the study please telephone Abratech's Research Coordinator, James Obayashi, at (415) 289-7458, or Abratech's Research Director, Dr. Don Jewett at (415) 2897455. If you have questions you do not wish to directly communicate to anyone at Abratech Corporation, you may contact the chair of Abratech's Institutional Review Board: Ms. Erica Heath at (800) 472-3241.

In closing, we thank you for your interest, and hope you will be able to participate in our study.

Sincerely,

James Obayashi, Research Coordinator

Abratech Corporation

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